## REMARKS

Applicant respectfully requests reconsideration. Claims 1-16 were previously pending in this application. By this amendment, claims 1-4, 10, 11, 15 and 16 have been amended, and new claims 17-24 have been added. As a result, claims 1-24 are pending for examination with claims 1, 15 and 18 being independent claims. No new matter has been added. Applicant respectfully requests reconsideration in view of these amendments and the following arguments.

Applicant would like to thank Examiner Gray for his courtesies during a telephone interview with Larry Green and Shannon Pratt on May 24, 2006. Several of the rejections were discussed. The substance of the discussion is incorporated into the following remarks.

Applicant would also like to thank Examiner Gray for mailing an Interview Summary Sheet on May 30, 2006. However, Applicant would like to clarify one statement in the Summary Sheet. It states that "Applicant's attorneys stated that their inventive method did not rely on the use of mechanical structures to control the pressure differences in the structure as does the prior art of record." This statement is not entirely accurate. To clarify, the prior art of record prevents upstream contamination solely with mechanical structures, such as valves. The inventive method may also use mechanical structures. However, unlike the prior art of record, the inventive method also uses a differential pressure to prevent upstream contamination. In this respect, even in the event that the mechanical structure fails, upstream contamination is still prevented due to the pressure difference between an intermediate pressure and the downstream pressure. In contrast, with the prior art of record, failure of a mechanical structure may lead to upstream contamination. As discussed in more detail below, the prior art of record does not teach or suggest the use of pressure differences to prevent the upstream flow of liquid.

### *Claim Objections*

In the Office Action dated February 7, 2006, the claims were objected to because they include reference characters not enclosed within parentheses and further because reference characters associated with independent claim 1 do not correspond with the reference characters associated with independent claim 15. In response to this objection, claims 1-4, 10, 11 15 and 16 have been amended to remove all reference characters.

Accordingly, withdrawal of this objection is respectfully requested.

***Rejections Under 35 U.S.C. §102***

*Heilman*

In the Office Action dated February 7, 2006, claims 1-2, and 4-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Heilman et al. (U.S. Patent No. 5,569,181). Applicant respectfully disagrees with this rejection. However, to further the prosecution of this application, Applicant has amended independent claim 1 to more clearly distinguish over Heilman. Applicant respectfully traverses the rejection of independent claim 15.

Heilman is directed to an apparatus for delivering contrast media to multiple patients either sequentially or simultaneously. A back-flow valve 21 positioned downstream of the contrast media reservoir mechanically prevents fluid from contaminating the reservoir. A plurality of disposable dosing units 40-42 are positioned at the downstream end of the apparatus for connection to patients. Each dosing unit includes another back-flow valve 46 and a sterility filter 47.

As pointed out in the Background Section in the present application, even though prior art devices (such as Heilman) may reduce the risk of backflow with non-return (back-flow) valves, there still remains the risk of fluid leaking through those valves. (page 1, lines 23-29). In an effort to address the problems associated with the prior art, aspects of the present invention are directed to a method which utilizes a differential pressure to prevent leakage and upstream contamination. Thus, in the event that a valve fails, any liquid located downstream of the intermediate segment will be prevented from contaminating upstream portions due to the pressure difference. In other words, in the event of a leak, the fluid will flow towards the lower pressure at the downstream end as opposed to flowing upstream.

Heilman does disclose increasing pressure by using a pressurizing pump 25. (Heilman, Col. 4, lines 22-28). However, this pump is only used to *inject* the fluid into the patient. It is known to use pressure to inject a fluid into a patient. In contrast, the differential pressure according to the present invention is specific to *when injection to the patient is desired to be stopped.*

Heilman also describes what may occur *after the injection.* However, when describing ways to preserve sterility of the device, Heilman does not teach or suggest utilizing a differential pressure. One approach discussed in Heilman separates the disposable dosing units by heat sealing the tube in two places and then cutting the tube between the two seals to preserve

sterility. (Heilman, Col. 6, lines 13-18). Another approach in Heilman uses a rotary valve in which the valve is simply rotated to the next position to maintain sterility. (Heilman, Col. 6, lines 34-42). Thus, Heilman does not teach or suggest *after the injection is stopped* to produce a greater intermediate pressure than the downstream pressure, as recited in independent claims 1 and 15.

During the telephone interview, the above differences between Heilman and the present invention were discussed. It was the Applicant's representatives' understanding that the Examiner understood this important distinction between Heilman and the present application. However, it appeared that the Examiner was concerned that Heilman still may read on claim 1 because closing the valves in Heilman would inherently produce a greater upstream pressure at the moment the valve is closed, although the Examiner admitted that this would only result in a transient pressure difference.

To further the prosecution of the application, and to alleviate the Examiner's concern, Applicant has amended claim 1 to clarify the claimed subject matter. In particular, as amended, independent claim 1 now recites a method of injecting liquid under pressure to a patient including the steps of providing liquid under pressure to a patient through a length of tubing, where the tubing includes a first occlusion system and a regulation system located upstream from the first occlusion system. The first occlusion system and the regulation system define an intermediate segment having an intermediate pressure and the tubing also includes a segment downstream of the first occlusion system having a downstream pressure. The method further recites when injection to the patient is desired to be stopped, closing the regulation system and the first occlusion system to produce a greater intermediate pressure than the downstream pressure, "*whereby the pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped.*"

As discussed, Heilman does not teach or suggest any type of pressure difference other than during a conventional *injection* process. Heilman furthermore does not teach or suggest a pressure difference that *prevents the upstream flow of fluid after the injection has stopped*, as now recited in independent claim 1. Applicant respectfully submits that claim 1 is patentable over Heilman, even if one were to take the position that Heilman may produce a transient pressure difference by shutting off a valve. In particular, a transient pressure difference would

quickly dissipate, such that this configuration would not prevent the upstream flow of liquid after the injection has stopped, as recited in claim 1.

For at least these reasons, claim 1 is patentable over Heilman. Claims 2 and 4-14 all depend from claim 1 and are patentable for at least the same reasons.

Accordingly, withdrawal of these rejections is respectfully requested.

Independent claim 15 recites a method of injecting liquid under pressure to a patient including the steps of providing liquid under pressure to a patient through a length of tubing, where the tubing includes a first occlusion system and a regulation system located upstream from the first occlusion system. The first occlusion system and the regulation system define an intermediate segment having an intermediate pressure, and the tubing also includes a segment downstream of the first occlusion system having a downstream pressure. The method further recites "*when injection to the patient is desired to be stopped, closing the regulation system to prevent liquid flow therethrough, and after closing of the regulation system, closing the first occlusion system to produce a greater intermediate pressure than the downstream pressure.*"

Heilman does not teach or suggest that when the injection is desired to be stopped to *first* close the regulation system and *thereafter* to close the first occlusion system to produce the pressure differential between the intermediate pressure and the downstream pressure, as recited in independent claim 15. As discussed above, Heilman does not discuss the use of any type of differential pressure other than during the injection. Furthermore, there is no discussion in Heilman about the order of closing any one valve in comparison to closing another valve. Thus, there is no explicit or even inherent disclosure of claim 15.

For at least these reasons, claim 15 is patentable over Heilman. Claim 16 depends from claim 15 and is patentable for at least the same reasons.

Accordingly, withdrawal of these rejections is respectfully requested.

*Lichtenstein*

In the Office Action dated February 7, 2006, claims 1-7, 10-13 and 15-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Lichtenstein (U.S. Patent No. 4,464,172). Applicant respectfully disagrees with this rejection. However, to further the prosecution of this application, Applicant has amended independent claim 1 to more clearly distinguish over Lichtenstein. Applicant respectfully traverses the rejection of independent claim 15.

Lichtenstein is directed to a computer-controlled device for performing a number of diagnostic procedures, including blood sampling and injecting fluids into a patient. As shown in FIGS. 2 and 3, the device includes a plurality of valves, sensors, and controllers.

Lichtenstein, like Heilman, discloses controlling pressure by using a pressurizing pump 25. (Lichtenstein, Col. 10, line 65 – Col. 11, line 3). However, this pump is only used to control fluid flow rates. Lichtenstein also discloses building up a pressure difference across membrane 46 with a pump. (Lichtenstein, Col. 13, lines 6-25). Membrane 46 is a semi-permeable membrane within a dialysis canister 42 where the pressure difference is part of the filtration process associated with dialysis. In contrast, the differential pressure according to the present invention is specific to *when injection to the patient is desired to be stopped.*

Lichtenstein discusses how the patient is isolated from the device when the flow of fluid to/from the patient is interrupted or terminated. However, the approaches discussed in Lichtenstein, like the prior art discussed in the present application, rely only on a mechanical structure. In particular, the patient is isolated by simply closing the valves or by interrupting the power supply to pumps or by interrupting gravity flow. According to Lichtenstein, closing a valve interrupts the flow of fluid, thus isolating the patient from the device so far as fluid transfer is concerned. (Lichtenstein, Col. 11, lines 52-63).

Thus, Lichtenstein, like Heilman does not teach or suggest *after the injection* to produce a greater intermediate pressure than the downstream pressure, as recited in independent claims 1 and 15. In contrast, Lichtenstein relies on a structure, such as a valve, to prevent leakage and/or upstream contamination.

As discussed above, independent claim 1 has been amended for clarity. In particular, claim 1 recites that the *pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped.*

There is no teaching or suggestion in Lichtenstein to provide this pressure difference to prevent the upstream flow of liquid after the injection has stopped. As discussed above, even if one were to take the position that Lichtenstein may produce a transient pressure difference at the moment a valve is closed, the transient pressure difference would soon dissipate, such that this configuration would not prevent the upstream flow of liquid after the injection has stopped, as recited in claim 1.

For at least these reasons, claim 1 is patentable over Lichtenstein. Claims 2-7 and 10-13 all depend from claim 1 and are patentable for at least the same reasons.

Accordingly, withdrawal of these rejections is respectfully requested.

Independent claim 15 is discussed above.

Lichtenstein, like Heilman does not teach or suggest that when the injection is desired to be stopped to *first* close the regulation system and *thereafter* to close the first occlusion system to produce the pressure differential between the intermediate pressure and the downstream pressure, as recited in independent claim 15. As discussed above, Lichtenstein does not discuss the use of any type of differential pressure after an injection, when the injection is desired to be stopped. Furthermore, there is no discussion in Lichtenstein about any order of closing one valve in comparison to closing another valve. Thus, there is no explicit or even inherent disclosure of claim 15.

For at least these reasons, claim 15 is patentable over Lichtenstein. Claim 16 depends from claim 15 and is patentable for at least the same reasons.

Accordingly, withdrawal of these rejections is respectfully requested.

*Teirstein*

In the Office Action dated February 7, 2006, claims 1-7, 9-13 and 15-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Teirstein (U.S. Patent No. 5,533,978). Applicant respectfully disagrees with this rejection. However, to further the prosecution of this application, Applicant has amended independent claim 1 to more clearly distinguish over Teirstein. Applicant respectfully traverses the rejection of independent claim 15.

Teirstein is directed to a method and apparatus for injecting a radiographic dye during angioplasty. The apparatus include a bottle 12 which holds the dye, and a one-way valve 36 which allows for the dye to only flow toward a deformable holding chamber 14. Downstream of the deformable chamber 14 is tubing 20 and a syringe 50 with a manifold 16 which may have a plurality of valves.

Terstein fails to teach or suggest any use of a differential pressure *when injection to the patient is desired to be stopped.* In contrast, Teirstein prevents upstream contamination by using one-way valves and also by the presence of an air gap in the holding chamber 14 which separates fluid in the bottle 12 from fluid in the holding chamber 14. (Teirstein, Col. 7, lines 5-40).

As discussed above, independent claim 1 has been amended for clarity. In particular, claim 1 recites that the *pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped.*

There is no teaching or suggestion in Teirstein to provide a pressure difference to prevent the upstream flow of liquid *after the injection has stopped.* Even if one were to take the position that Teirstein may produce a transient pressure difference at the moment a valve is shut off, the transient pressure difference would soon dissipate, such that such a configuration would not prevent the upstream flow of liquid after the injection has stopped, as recited in claim 1.

For at least these reasons, claim 1 is patentable over Teirstein. Claims 2-7 and 9-13 all depend from claim 1 and are patentable for at least the same reasons.

Accordingly, withdrawal of these rejections is respectfully requested.

Independent claim 15 is discussed above.

Teirstein, like Lichtenstein and Heilman discussed above, does not teach or suggest that when the injection is desired to be stopped to *first* close the regulation system and *thereafter* to close the first occlusion system to produce the pressure differential between the intermediate pressure and the downstream pressure, as recited in independent claim 15. Teirstein does not discuss the use of any type of differential pressure after an injection. Furthermore, there is no discussion in Teirstein about any order of closing one valve in comparison to closing another valve. Thus, there is no explicit or even inherent disclosure of claim 15.

For at least these reasons, claim 15 is patentable over Teirstein. Claim 16 depends from claim 15 and is patentable for at least the same reasons.

Accordingly, withdrawal of these rejections is respectfully requested.

***New Claims***

Applicant has added new claims 17-24, including independent claim 18 to further define the invention. Support for the new claims may be found at least on page 2, lines 19-26, page 2, line 30-page 3, line 2, page 5, lines 12-14, and page 10, lines 10-13.

New independent claim 18 is directed to a method of injecting liquid under pressure to a patient. The method comprising the steps of providing liquid under pressure to a patient through a length of tubing, where the tubing includes a first occlusion system and a regulation system located upstream from the first occlusion system. The first occlusion system and the regulation

system define an intermediate segment having an intermediate pressure. The tubing also including a segment downstream of the first occlusion system having a downstream pressure. The method further comprises the step that when injection to the patient is desired to be stopped, closing the regulation system and the first occlusion system to *maintain* a greater intermediate pressure than the downstream pressure *at least until the patient is disconnected from the tubing.*

As discussed during the telephone interview, the Examiner was concerned that the above described references may inherently produce a transient pressure difference at the moment a valve is closed. However, even if this were so, new independent claim 18 is clearly distinguishable. In particular, independent claim 18 recites that a greater intermediate pressure is *maintained at least until the patient is disconnected from the tubing.*

New claims 19-24 depend from new claim 18 and are patentable for at least the same reasons as claim 18.

New claim 17 depends from claim 15 and is patentable for at least the same reasons as claim 15. Furthermore, the recitation that an opening pressure of the regulation system is greater than an opening pressure of the first occlusion system to prevent any fluids in the intermediate segment from moving upstream through the regulation system is neither disclosed nor suggested by Heilman, Lichtenstein or Teirstein.

## CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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